



January 19, 2022

Carol Cole Company  
Bob Duffy  
President  
16405 Summer Sage Rd  
Poway, California 92064

Re: K120560

Trade/Device Name: Trinity Wrinkle Remover

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory Class: Class II

Product Code: OHS

Dear Bob Duffy:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated November 6<sup>th</sup>, 2012. Specifically, FDA is updating this SE Letter with a corrected 510(k) Summary, which includes the correct device characteristics, as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Purva Pandya, OHT4: Office of Surgical and Infection Control Devices, 240-402-9979, [purva.pandya@fda.hhs.gov](mailto:purva.pandya@fda.hhs.gov).

Sincerely,

**Purva U. Pandya -S**

Purva Pandya  
Assistant Director  
DHT4A: Division of General Surgery Devices  
OHT4: Office of Surgical  
and Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-002

Carol Cole Company  
% Bob Duffy Associates, Incorporated  
Mr. Bob Duffy  
President  
16405 Summer Sage Road  
Poway, California 92064

November 6, 2012

Re: K120560

Trade/Device Name: Trinity Wrinkle Remover

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory Class: Class II

Product Code: OHS

Dated: October 28, 2012

Received: October 31, 2012

Dear Mr. Duffy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): K120560

Device Name: Trinity Wrinkle Remover

#### Indications For Use:

The Trinity Wrinkle Remover is an over-the-counter hand-held device intended for the use in the treatment of full-face wrinkles.

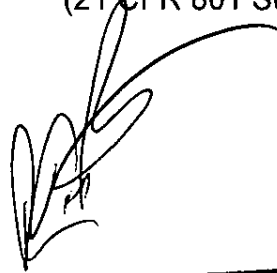
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ AND/OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use X  
(21 CFR 801 Subpart C)



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(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K120560

## **510(k) Summary**

### **Trinity Wrinkle Remover**

**Prepared:** December 15, 2021

#### **CONTACT INFORMATION**

Carol Cole Company  
3146 Tiger Run Court; Suite 109  
Carlsbad, California 92010

*Phone:* (760) 734-4545

*Facsimile:* (760) 734-4565

*Email:* [tvaldez@mynuface.com](mailto:tvaldez@mynuface.com)

*Contact Person:* Tera Valdez, Vice President

#### **DEVICE NAME**

*Trade Name:* Trinity Wrinkle Remover

*Common Name:* Light based over the counter wrinkle reduction device

*Classification Name:* Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)

Product Code: OHS

#### **PREDICATE DEVICES**

The Carol Cole Company is claiming substantial equivalence to the following devices:

1. Light for Wrinkles device, cleared under 510(k) K101190
  - a. Device Proprietary Name: Light for Wrinkles
  - b. Manufacturer: LED Intellectual Properties, LLC
  - c. Product Code: OHS
  - d. Indications for Use: The Light for Wrinkles is an over-the-counter handheld device intended for the use in the treatment of periorbital wrinkles.
2. Light For Wrinkles Device, Cleared under 510(k) K120775
  - a. Device Proprietary Name: Light for Wrinkles
  - b. Manufacturer: LED Intellectual Properties, LLC
  - c. Product Code: OHS
  - d. Indications for Use: The LightStim for Wrinkles is an Over-The Counter handheld device intended for the use in the treatment of full-face wrinkles

The Trinity Wrinkle Remover is a new device design based on portions of the NuFACE® Trinity Facial Toning Device, which was cleared under K103472. The main body of the NuFACE® Trinity Facial Toning Device is used in conjunction with a new Treatment Head, that emits energy in the Red and IR region of the spectrum for reducing fine lines and wrinkles.

#### **INDICATIONS FOR USE/INTENDED USE**

The Trinity Wrinkle Remover is an over-the-counter hand-held device intended for the use in the treatment of full-face wrinkles.

## **TECHNOLOGICAL CHARACTERISTICS**

The Trinity Wrinkle Remover is an over-the-counter hand-held device for the use in the treatment of full-face wrinkles. It emits energy in the red and IR regions of the spectrum to reduce fine lines and wrinkles. The Subject device emits light energy at near identical levels as the Predicate device at the 605nm, 630nm, 660nm and 855nm wavelengths. The Subject device measured output spectral characteristics are identical to those of the Predicate device.

The device measures 3" W x 5.25" L x 1.25" D. Its outer case is injection molded of thermoplastic resin. The detachable Treatment Head comprises (36) Light Emitting Diodes (LED's) which emit light at the 605nm, 630nm, 660nm and 855nm wavelengths. The device is powered by 4 rechargeable batteries. The Trinity Wrinkle Remover comes with a Charging Cradle, which measures 3.25" W x 4" L x 3.25" D, to charge the internal batteries when not in use. The Charging Cradle is powered by d.c. power from a pre-approved wall-mount Power Supply provided with the device. All charging circuitry is contained within the handheld unit itself.

The Trinity Wrinkle Remover Treatment Head is designed for optimal contact with the face. The device continually pulses the LEDs output, and provides a fixed output intensity level. The device does not allow the output level to be changed. The '+' and '-' keys on the handle (main body) are not active when the Trinity Wrinkle Remover treatment Attachment is attached to the handle.

An ascending sequence of three audible beeps informs the User the device is ready for use. When the user turns off the device, a descending audible tone is emitted.

To promote proper use, a single audio beep every three minutes informs the user to relocate the device to treat a new location on the skin.

## **COMPLIANCE DATA**

The Trinity Wrinkle Remover was tested and found to conform to International Standard IEC 62471:2006 for the Photobiological safety of lamps and lamp systems.

The Trinity Wrinkle Remover was also tested and found to be in compliance with IEC 60601-1-2 for Electromagnetic Compatibility (EMC). The Trinity Wrinkle Remover was evaluated and found to be in compliance with IEC 60601-1 for Electrical Safety.

## **SUBSTANTIAL EQUIVALENCE**

The Trinity Wrinkle Remover has the same intended use and indications for use as the predicate devices. The Trinity Wrinkle Remover emits Red and IR energy at the same wavelengths and similar intensities as the predicate device.